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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/164,862	10/01/1998	PAUL A. PRICE	023070-08672	7170

22798 7590 03/15/2006

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/164,862	Applicant(s) PRICE ET AL.	
	Examiner Susan Ungar	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18, 38, 39, 47, 49 and 56-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-18, 38-39, 47, 49, 56-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed December 27, 2005 in response to the Office Action of September 23, 2005 is acknowledged and has been entered. Previously pending claims 1, 38, 47 have been amended. Claims 1-18, 38-39, 47, 49, 56-67 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

New Grounds of Rejection

Claim Rejections - 35 USC 112

4. Claims 1-18, 38-39, 47, 49, 56-67 are rejected under 35 USC 112, first paragraph as the specification does not contain a written description of the limitation newly added to claims 1, 38 and 47, "greater than the 95th percentile for YKL-40", in the specification and the claims as originally filed. A review of the specification reveals support for the 95th percentile being defined as the upper normal value of YKL-40 in a study of patients with bacterial pneumonia in Example 12, reveals support for median level of YKL-40 was 3.5 times higher than that of the upper 95th percentile of controls in a study of patients with bacterial pneumonia, again in Example 12, reveals support for the number of colon cancer patients being above the age-corrected 95th percentile of normal controls is 159 in Example 7. However, no support is found for the broadly claimed limitation that a sample YKL-40 value greater than the 95th percentile for YKL-40 levels in the same sample from normal healthy humans is an indicator of a reduced survival expectancy compared to patients with normal YKL-40 value. Although a review of the specification reveals support for YKL-40 level above the 95% level of 120 normal women correlating to decreased survival in patients with breast cancer (see

page 4) wherein 95% level is only disclosed in the specification as referring to confidence interval (see page 66), this does not provide support for the newly claimed limitations because confidence interval and percentile are two very different parameters. In particular, wherein confidence intervals are the likely range of a true value wherein this interval is dependent, among other things, upon the number of subjects for the correlation coefficient, the percentile is drawn only and specifically to a defined level of a population that is divided into 100 equal parts.

Applicant's arguments drawn to the rejection of claims 1-18, 53, 54, 67 under 35 USC 112, first paragraph in the paper mailed September 23, 2005, Section 3, pages 3-6 are relevant to the instant rejection.

Applicant argues that since claims 1-18, 53, 54 and 67 were rejected by Examiner under a scope of enablement rejection under 35 U.S.C. 112, first paragraph, wherein Examiner stated that the specification is enabling for methods where a "YKI--40 level greater than the 95th percentile for normal control YKI-40 levels is an indicator of reduced survival expectancy . . .", amendment of the claims to recite this limitation obviates the scope rejection. The argument has been considered but has not been found persuasive because although the amendment of the claims obviates the prior grounds of rejection, Examiner must be assume that Applicant is aware that MPEP 1504.04 specifically teaches in-part that

An amendment to the claim which has no antecedent basis in the specification and/or drawings as originally filed introduces new matter because that subject matter is not described in the application as originally filed. The claim must be rejected under 35 U.S.C. 112, first paragraph.

Although the prior art and post-filing references previously submitted, drawn to breast cancer (not claimed in the instant application), clearly teach the

enablement of the claims using the 95th percentile level, this does not overcome the absence of support for the claimed amendment in the specification.

5. All other objections and rejections recited in the previous office action are hereby withdrawn.

6. No claims allowed.

7. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

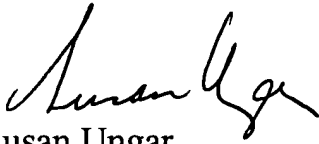
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

Art Unit: 1642

application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

A handwritten signature in black ink, appearing to read "Susan Ungar". The signature is fluid and cursive, with the first name "Susan" written in a larger, more prominent script than the last name "Ungar".

Susan Ungar

Primary Patent Examiner

March 10, 2006